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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,326	03/30/2004	Per Gisle Djupesland	FRYHP0101USC	5109

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,326

Applicant(s)

DJUPESLAND, PER GISLE

Examiner

Michael G. Mendoza

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10 and 19-34 is/are rejected.
- 7) ☒ Claim(s) 7, 9, and 11-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8 and 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 8 recites the limitation "the step of controlling" in line 1. There is insufficient antecedent basis for this limitation in the claim.

4. As to claim 30, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 30 recites the broad recitation nasal inflammation, and the claim also recites rhinitis which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 10, 21, 26, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Keldmann et al. WO 98/53869 as evidenced by Grossan 3847145.

7. Keldmann et al. teaches a method of delivering a substance to the nasal airway of a subject, comprising the steps of: sealing one the nostrils of a subject to an outlet of a delivery unit such as to prevent the escape of gas flow through the one nostril; closing the oropharyngeal velum of the subject; and delivering a gas flow entraining a substance through the outlet at a driving pressure. It would be inherent that if one nostril is sealed and is receiving gas flow, and the oropharyngeal velum is closed, that the only way for the gas flow to escape is around the posterior margin of the nasal septum and out of the other nostril of the subject as evidenced by Grossan. Grossan describes the flow of fluid through one nostril and out the other when one nostril is sealed to an outlet dispensing a fluid (see abstract lines 25-30). Keldmann et al. teaches the method of claim 1, wherein the velum closure step is provided by exhalation by the subject; wherein the exhalation is through a flow resistor (pg. 3, lines 9-23); wherein the gas flow entraining a substance is provided by the exhalation flow of the subject; wherein the substance comprises a dry powder; wherein the substance contains a medicament,

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particularly for the treatment of a nasal condition; and delivering a substance to the posterior region of the nasal airway.

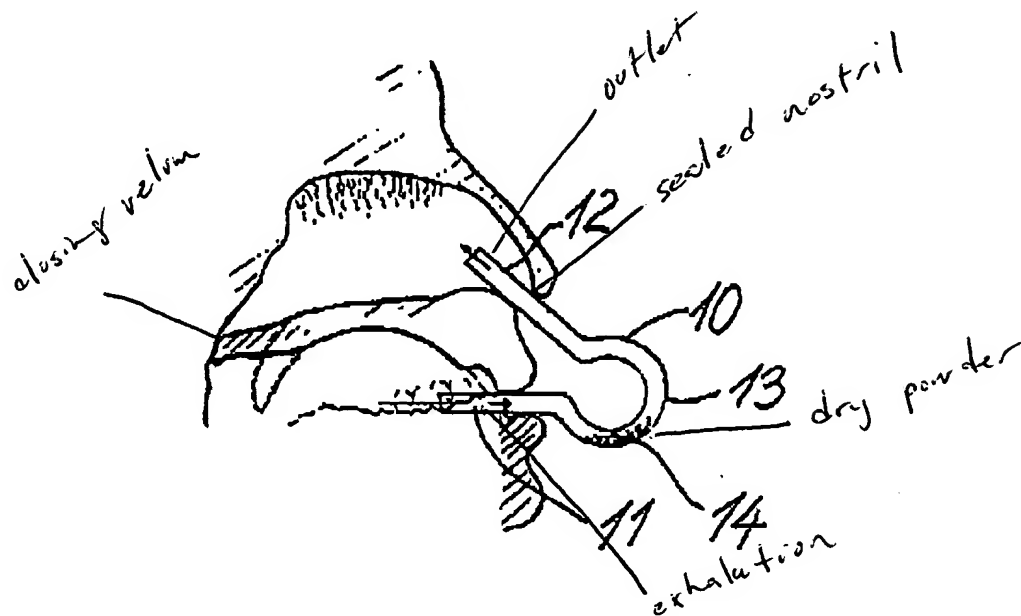


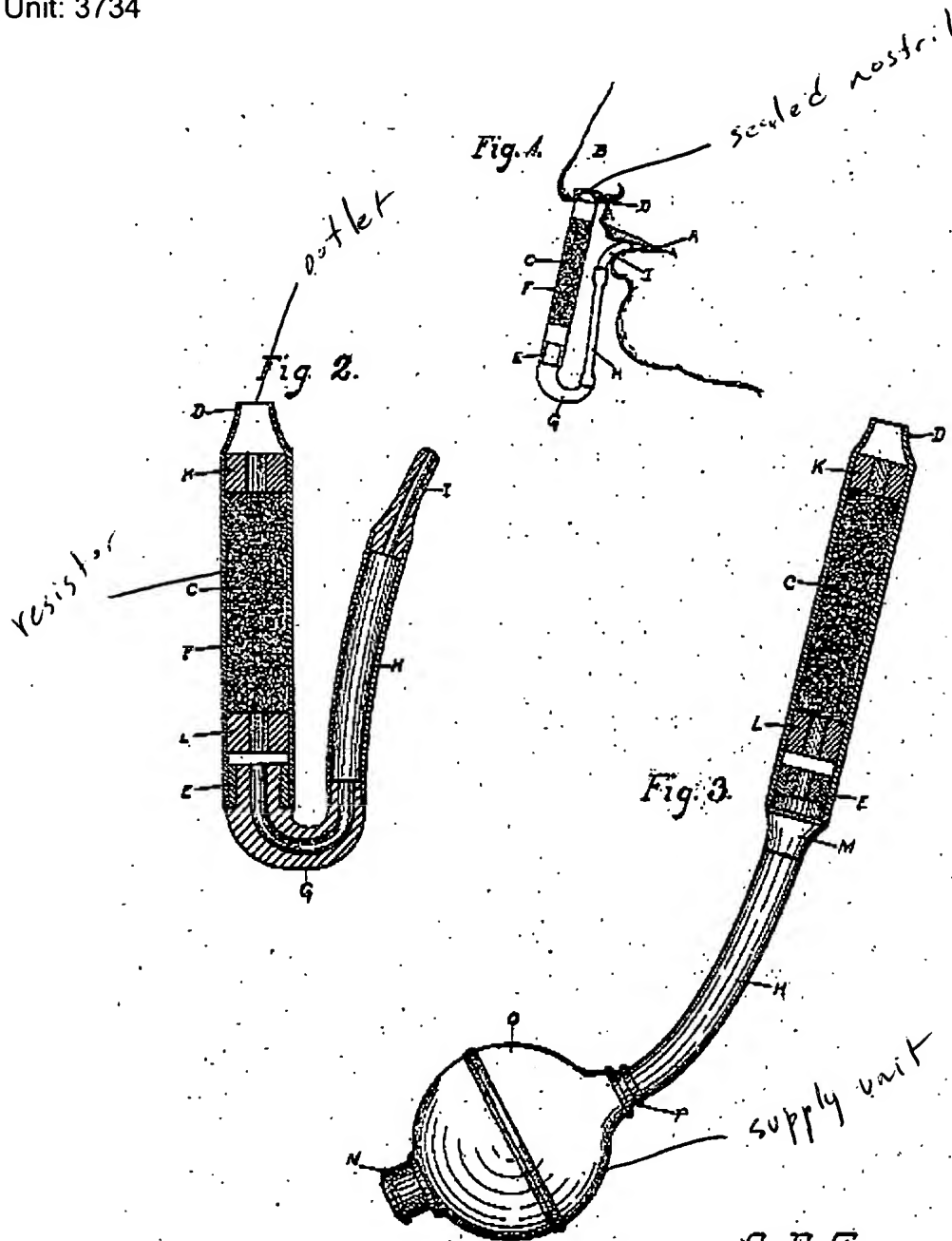
Fig. 1

8. Claims 1-3, 5, 6, 21-23, and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Seidel 746749.

9. Seidel teaches a method of delivering a substance to the nasal airway of a subject, comprising the steps of: sealing one the nostrils of a subject to an outlet of a delivery unit such as to prevent the escape of gas flow through the one nostril; closing the oropharyngeal velum of the subject; and delivering a gas flow entraining a substance through the outlet at a driving pressure. It would be inherent that if one nostril is sealed and is receiving gas flow, and the oropharyngeal velum is closed, that the only way for the gas flow to escape is around the posterior margin of the nasal septum and out of the other nostril of the subject as evidenced by Grossan. Grossan describes the flow of

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fluid through one nostril and out the other when one nostril is sealed to an outlet dispensing a fluid (see abstract lines 25-30). Seidel teaches the method of claim 1, wherein the velum closure step is provided by exhalation by the subject (pg. 2, lines 22-34); wherein the exhalation is through a flow resistor (pg. 2, lines 7-9); wherein the gas flow entraining the substance is provided by actuation of a supply unit (pg. 2, lines 47-55); wherein the gas flow is separate to the exhalation flow of the subject; wherein the substance comprises a dry powder; wherein the substance comprises liquid droplets; wherein the liquid droplets comprise one of a solution or a suspension (pg. 1, lines 49-50); wherein the substance contains a medicament, particularly for the treatment of a nasal condition; wherein the substance comprises a cleansing agent for cleansing the nasal airway; wherein the substance comprises an irrigating agent for irrigating the nasal airway (pg. 1, lines 49-50); and delivering a substance to the posterior region of the nasal airway.



Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 3, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keldmann et al.

12. As to claim 3, Keldmann et al. fails to specifically teach wherein the flow resistor is configured to maintain a positive pressure differential of at least about 5 cm H₂O. However, Keldmann et al. is fully capable of meeting the recited limitations. Keldmann et al. teaches an adjustable resistor that can be adjusted to the claim limitations (pg. 3, lines 9-23).

13. As to claims 24 and 25, Keldmann discloses the claimed invention except for a particle size distribution in the range of about 1 to 10 μ m. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, USPQ 233.

14. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keldmann et al. in view of Butler et al. 5937852.

15. Keldmann et al. teaches the delivery device of 1. It should be noted that Keldmann et al. fails to teach the delivery unit further comprising an indicator.

Butler et al. teaches a delivery device with a common indicator as visual stimulus.

Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Keldmann et al. to include the indicator of Butler et al. to indicate when the user is actually exhaling (col. 2, line 67 – col. 3, line 1).

16. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keldmann et al. and Seidel.

17. The inventions of Keldmann et al. and Seidel a device for dispensing an agent through the nostril of a subject. Any type of agent can be used within the devices depending on the ailment of the subject. The devices of Keldmann et al. and Seidel can be used to treat nasal ailments including the limitations of the claims 31-34.

Allowable Subject Matter

18. Claims 7, 9, 11-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MM



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER